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GUPTA, VANI	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/596,434
Filing Date: June 13, 2006
Appellant(s): GERARD ET AL.

W. Brinton Yorks, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 3, 2012 appealing from the Office action mailed August 15, 2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1 – 14 are pending and claims 1 – 14 stand finally rejected by the Office action of August 15, 2011.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,574,492 B1	Ben-Haim et al.	6-2003
5,357,550	Asahina et al.	10-1994
6,233,477 B1	Chia et al.	5-2001
2004/0254454 A1	Kockro	12-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. ***Claims 1 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6,574,492 B1) in view of Chia et al. (6,233,477 B1) in view Asahina et al. (US 5,357,550).***

Regarding Claim 1, *Ben-Haim et al.* (hereinafter *Ben-Haim*) suggests a medical system comprising:

a medical instrument *(catheter #1)* to be guided in a patient body *(col. 3, ll. 3 – 5)*; and an

X-Ray acquisition means capable of acquiring a two-dimensional X-ray image of said medical instrument *(col. 33, ll. 53 – 59).*

Ben-Haim also suggests a second catheter *(catheter #2)* that is capable of acquiring a three-dimensional location/positional data set of said medical instrument *(col. 13, ll. 4 – 6; and col. 23, ll. 28 – 40).*

Ben-Haim also suggests that the catheter #2 may be localized or imaged by the X-ray acquisition means *(col. 23, ll. 53 - 59).* Ben-Haim is capable of providing localization of catheter #2 within a referential of said X-ray acquisition means. More specifically, Ben-Haim suggests "mapping" the coordinates of the catheter #2 to the x-ray imaging means. (col. 33, ll. 53 – 59). it would be understood by one of ordinary skill in the art that this visualization of the catheter by the x-ray imaging means, which is used to assist in determining the position of the catheter with respect to the heart, would correspond also to the position of the catheter to the x-ray imaging means, since the "referencing of the mapping of the propagation of electrical impulses of the heart" would mean that the calculated/determined position of the heart would include the position of the heart with respect to x-ray imaging means. Additionally, it would be obvious to one skilled in the art that this would require some kind mathematical or algorithmic processing by the x-ray imaging means to convert the catheter #2 coordinates into the x-ray referential coordinates.

Ben-Haim differs from Claim 1 in that Ben-Haim does not suggest that *catheter #2* comprises an ultrasound acquisition means using an ultrasound probe (or transducer) to acquiring a three-dimensional location/positional (ultrasound) data set of said medical instrument.

Nonetheless, Chia et al. *(hereinafter Chia)* provides a dual-catheter system wherein one of the catheter tracks the position of the second catheter with the use of an ultrasound imaging transducer located on the first catheter *(col. 2, line 39 – col. 3, line 3; col. 3, line 58 – col. 4, line 3; and col. 4, ll. 32 – 33 and 41 – 42).*

Additionally, Asahina et al. (hereinafter Asahina) suggests that it is possible to visualize an ultrasound probe on an x-ray (or tomographic) image to provide a combined ultrasound and x-ray (or tomographic) image *(Abstract; col. 2, ll. 49 – 60; col. 5, ll. 37 – 40; and col. 5, ll. 56 – 67).*

Furthermore, Ben-Haim in view of Chia is capable of selecting a region of interest around said medical instrument in the three-dimensional ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition means.

Furthermore, Ben-Haim in view of Chia in view of Asahina is capable of converting said first localization of said region of interest within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe, and capable of generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization, as this only requires processor capabilities, which are

disclosed by Asahina *("image processor," **(14)**)*, by Ben-Haim *("computer," (51))*, and by Chia *("data acquisition computer," **(38)**)*.

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Haim and Chia before one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system teachings of Ben-Haim with dual-catheter-positioning-system using ultrasound imaging teachings of Chia so that one could obtain optimal 3D localizing of the medical instrument *(Chia: col. 4, line 9)*.

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Haim in view of Chia and Asahina before one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system using ultrasound imaging teachings of Ben-Haim in view Chia with the x-ray "radiographing" of an ultrasonic probe of Asahina so that one could obtain additional image-based information about the medical instrument by using a dual-imaging system *(Asahina: col.5, ll. 31 – 55)*.

Regarding claims 2 – 5 and 9 – 13, Ben-Haim in view of Chia in view of Asahina is capable of performing claimed functions as they only require the use of a processor, which is disclosed by Ben-Haim, Chia, and Asahina, as discussed in the rejection of Claim 1 above.

Regarding claims 7 and 8, Ben-Haim in view of Chia in view of Asahina suggests a system as claimed in claim 1, wherein said ultrasound probe is equipped with at least three non aligned and interdependent radio-opaque markers *("piezoelectric markers") (see aforementioned citations of Chia)* and said localization means are intended to localize said markers in at least a first 2D X-ray image having a first orientation angle in said referential *(Asahina: col. 5, ll. 56 – 61 and col. 6, ll. 21 – 24)*; and wherein said localization means (via processor) are capable of

further localize said markers in a second 2D X-ray image having a second orientation angle in said referential.

2. ***Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim in view of Chia in view Asahina in view of Kockro (US PG Pub 2004/0254454 A1).***

Regarding Claim 14, *Ben-Haim in view of Chia in view of Asahina* suggests a medical system comprising:

acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system, acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system, and localizing said ultrasound probe in a referential of said X-ray acquisition system *(see rejection of Claim 1).*

However, Ben-Haim in view of Chia in view of Asahina differs from Claim 14 in that Ben-Haim in view of Chia in view of Asahina does not suggest specifically selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system.

Nonetheless, Kockro suggests selecting a region of interest (by using of a "bounding box") of a tracked medical instrument (i.e. said region of interest defined as target of medical instrument) within a 3D image data set that define a first localization of said region of interest within a referential of the imaging system (paragraphs [0045 – 0046].

Ben-Haim in view of Chia in view of Asahina suggests converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system by virtue of the fact that the ultrasound catheter probe is being tracked by the X-ray acquisition system (see rejection of Claim 1).

Ben-Haim in view of Chia in view of Asahina generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization *(Asahin: col. 5, line 27 – col. 6, line 24).*

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Haim in view of Chia in view of Asahina and Kockro before one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system using ultrasound imaging with the x-ray "radiographing" of an ultrasonic probe teachings of Ben-Haim in view of Chia in view of Asahina with the bounding box teachings of Kockro so that one could obtain a more realistically" corresponding position of the medical instruemnt with respect to the corresponding imaging system *(Kockro: paragraph [0046]).*

(10) Response to Argument

Applicant's first argument: "At the very end of the description Ben-Haim et al. say that the positions of the catheters in relation to the heart can be visualized with X-ray or ultrasound. How this is done is not explained."

In response to Applicant's first argument: Examiner disagrees respectfully. In col. 33, ll. 53 – 59, Ben-Haim suggests that "ultrasound or X-ray imaging may be used to determine the position of the first and/or second catheter in relation to the heart, so as to verify the reference points of the mapping of propagation of electrical impulses in the heart. In this case, the catheter to be imaged must include a suitable radio-opaque or ultrasound-reflecting marker." As explained above in the rejection of Claim 1, it would be understood by one of ordinary skill in

the art that this visualization of the catheter by the x-ray imaging means, which is used to assist in determining the position of the catheter with respect to the heart, would correspond also to the position of the catheter to the x-ray imaging means, since the "referencing of the mapping of the propagation of electrical impulses of the heart" would mean that the calculated/determined position of the heart would include the position of the heart with respect to x-ray imaging means. Additionally, it would be obvious to one skilled in the art that it would require some kind mathematical or algorithmic processing by the x-ray imaging means to convert the catheter #2 coordinates into the x-ray referential coordinates.

Applicant also argues: "There is also no use of three-dimensional ultrasound by Ben-Haim et al.

In response to Applicant's argument: Examiner directs respectfully Applicant to Ben-Haim, who suggests that second catheter *(catheter #2)* acquires *three-dimensional location/positional data* of the first catheter *(col. 13, ll. 4 – 6; and col. 23, ll. 28 – 40).* Chia et al. *(hereinafter Chia)* provides a dual-catheter system – a dual-catheter system that operates in much the same way as the dual-catheter system of Ben-Haim – wherein *one of the catheter tracks the position of the second catheter with the use of an ultrasound imaging transducer located on the first catheter (col. 2, line 39 – col. 3, line 3; col. 3, line 58 – col. 4, line 3; and col. 4, ll. 32 – 33 and 41 – 42).* Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

That is to say, the combination of Ben-Haim and Chia provides a teaching of use of three-dimensional ultrasound. Please see rejection of Claim 1 for details.

Applicant's argues also: "No bi-modal representations are made by Ben-Haim et al."

In response to Applicant's argument: As explained in an aforementioned response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. That is to say, the combination of references (Ben-Haim, Chia, and Asahina) provides a teaching of a generation of a bi-modal x-ray image. Please see rejection of Claim 1 for details.

Applicant's second argument: "Chia et al. describe a pair of catheters with ultrasound crystals at their tips which serve as beacons. This enables the tip of one catheter to do ranging with the other catheter. No imaging at all is done by Chia et al., only 3D ultrasound locating with the ranging system."

In response to Applicant's second argument: Chia et al. is used to modify or supplement Ben-Haim. As explained above, Ben-Haim provides dual catheter system, wherein one catheter tracks the position of a second catheter. However, Ben-Haim is silent with respect to whether this positional data is ultrasonic in nature, as explained in the rejection of Claim 1. This is where Chia et al. comes in. Chia et al. provides the teachings that suggests, as per the cited passages, that a dual-catheter system may operate with use of ultrasound technology, wherein the first (locator) catheter detects signals from ultrasonic crystals placed on the catheters *(col. 2, line 39 – col. 3, line 3; col. 3, line 58 – col. 4, line 3; and col. 4, ll. 32 – 33 and 41 – 42).*

Chia et al. suggests, while not going into specifics, also that these crystals may be used in "ultrasound imaging means" (col. 3, line 54), which reasonably suggests that Chia may be able to produce ultrasound images via these use of these crystals. Thus, as would be understood by one ordinary skill in the art, it would be reasonable to suggest that this locational information may be visual (imageable) in nature. Asahina et al. comes in for the specifics on ultrasound imaging via a catheter such as the aforementioned second catheter by Ben-Haim and Chia et al.; and the probes ability to be visualized by x-ray.

Applicant argues also: "No bi-modal representations are made by Chia et al., either."

In response: As explained in an aforementioned response, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. That is to say, the combination of references (Ben-Haim, Chia, and Asahina) provides a teaching of a generation of a bi-modal x-ray image. Please see rejection of Claim 1 for details.

Applicant's third argument: Asahina et al. are doing x-ray fluoroscopy and ultrasound imaging. Asahina et al. are not using 3D ultrasound, as made clear by their references to "frame memories" for the 2D image frames. Ultrasound images and fluoroscopy images are shown on separate displays, but time-matched so that concurrently acquired fluoroscopy and ultrasound images can be retrieved and shown at the same time."

In response to Applicant's third argument: Examiner disagrees respectfully and directs Applicant to col. 2, ll. 27 – 48 of Asahina, wherein it is discussed ultrasonic imaging may be accomplished via an ultrasonic probe/catheter. With respect to "frame memories," Asahina

explains that the ultrasonic image memory comprises a plurality of these. That is to say, frame memories are how the ultrasonic image data is stored in the memory. This does not suggest that the image data or frame memories are not ultrasonic in nature. In col. 5, ll. 56 - 67, Asahina discusses acquiring images of the ultrasonic imaging catheter itself, using x-ray fluoroscopy. As suggested by the Applicant, Asahina teaches time-matching the x-ray and ultrasonic data (col. 9, line 65 – col. 10, line 13). Therefore, the locational/postional data of the ultrasonic probe is mappable or convertible to the x-ray reference system.

Applicant argues also that Asahina et al. are not forming bimodal images, either.

In response: As explained in an aforementioned response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. That is to say, the combination of references (Ben-Haim, Chia, and Asahina) provides a teaching of a generation of a bi-modal x-ray image.

To summarize Examiner's responses and rejections, as provided above:

Ben-Haim provides catheter #1 – the medical instrument; the x-ray acquisition means that acquires 2D images said medical instrument; catheter #2 that tracks location of catheter #1. Catheter #2 may be localized or images by the x-ray acquisition means; thus, catheter #1 may be tracked with respect to the x-ray acquisition means. Tracking information is three-dimensional in nature. Ben-Haim does not go into details about the mode (e.g. electromagnetic, fluoroscopic, ultrasonic, etc.) of the tracking information provided by catheter #2.

Chia suggests that tracking information may be ultrasonic. Chia suggests also that the tracking information is three-dimensional in nature. Chia, just as Ben-Haim teaches, suggests

using dual-catheter system; i.e. one catheter tracks the location/position of a second catheter. Chia hints at the possibility of obtaining ultrasonic images as representation of this locational/ positional information. One would want to combine Ben-Haim with Chia to obtain optimal 3D localizing of the medical instrument *(Chia: col. 4, line 9).* Additionally, by combining Ben-Haim with Chia, one would be capable of selecting a region of interest around said medical instrument in the three-dimensional ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition means. That is, one would be able to narrow the region of interest around, or within the vicinity of, the medical instrument based upon the coordinates of that region of interest, because the coordinates of the medical instrument would already be known by Ben-Haim in view of Chia.

Asahina goes into specifics about generating ultrasonic images via a catheter/probe and how it is possible to visualize such an ultrasound probe on an x-ray (or tomographic) image to provide a combined ultrasound and x-ray (or tomographic) image *(Abstract; col. 2, ll. 49 – 60; and col. 5, ll. 37 – 40; and col. 5, ll. 56 – 67).* Additionally, as explained in the above response pertaining to Asahina, the locational/postional data of the ultrasonic probe is mappable or convertible to the x-ray reference system.

Additionally, as explained in the rejection of Claim 1, by combining Ben-Haim and Chia with Asahina, one would be capable of converting said first localization of said region of interest within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe (as explained by combination of Ben-Haim and Chia); and capable of generating and displaying a bi-modal representation of said medical instrument in which said

two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization, as explained by the combination of Ben-Haim and Chia with Asahina (see end of rejection of Claim 1, as presented above).

Therefore, the combination of references of Ben-Haim, Chia, and Asahina read on Claim 1 and its dependent claims 2 – 13. Therefore, as per claims 1 – 13, the combination of Ben-Haim, Chia, and Asahina provides a bi-modal representation of the medical device (or catheter #1).

Applicant's fourth argument: "Kockro describes a system which produces a heads-up display in front of a surgeon in which the surgeon can visualize CT or MRI images of a surgical site such as the head. Using a probe 9, the surgeon can manipulate the data in space. Like the other three references, Kockro lacks any use of 3D ultrasound data and does not show or suggest bimodal representations of a 2D X-ray image in a 3D ultrasound dataset."

In response to Applicant's fourth argument: As explained above, Ben-Haim in view of Chia in view of Asahina suggests acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system, acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system, and localizing said ultrasound probe in a referential of said X-ray acquisition system *(see rejection of Claim 1 and responses above).*

Applicant also argues: "The Examiner says that a 'bounding box' constitutes selecting the region of interest of a medical instrument, but a reading of the cited passage says that the

bounding box only delineates the surgical site, in this patent, surrounding the head. A surgical instrument could be anywhere in the head and is thus not spatially defined by the box."

In response to Applicant's arguments: Examiner points out respectfully that Claim 14 requires that one "*select a region of interest* of said medical instrument with the ultrasound data set." Examiner interprets this to mean the one is selecting the region of interest itself, as it is defined by the intended target of the medical instrument. This is what is being explained in the rejection of Claim 14. This is also what Examiner explained in the previous rejection: "...region surgical site comprises the medical/surgical instrument, and as the bounding box defines the entire surgical site *with respect to* the medical/surgical instrument, the bounding box provides localization of the "region of interest 'of said' the medical instrument." Examiner states surgical site *with respect to* the medical/surgical instrument to means the region of interest as defined as the area to be "worked on" by the surgical instrument.

Accordingly, Examiner submits respectfully that Claim 14 is rejected by these four patents as presented above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Vani Gupta/

Examiner, Art Unit 3777

Conferees:

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777

/THOMAS J SWEET/

Supervisory Patent Examiner, Art Unit 3738